KANSAS STATE BOARD OF PHARMACY MINUTES OF THE MEETING

September 20 & 21, 2005 ClubHouse Inn & Suites 924 SW Henderson Topeka, Kansas

Tuesday, September 20, 2005

MEMBERS PRESENT: Merlin McFarland, RPh., President; JoAnne Gilstrap, RPh., Vice President; Max Heidrick, RPh.; Dr. Shirley Arck, RPh.; and Michael Coast, R.Ph.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Melissa Martin, Compliance Officer; LaTonyua Rice, R.Ph., Pharmacy Inspector; Reyne Kenton, Compliance Officer; and Randy Forbes, General Counsel and Camille Nohe, Assistant Attorney General.

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: Merlin McFarland, President, called the meeting to order at 9:00 a.m.

APPROVAL OF AGENDA. A motion was made and seconded to approve the agenda as amended. The amendment deleted David Wendover from the Tuesday agenda scheduled for 2:15 p.m. (Heidrick/Coast) Motion carried 4-0.

APPROVAL OF JUNE 2005 MINUTES A motion was made and seconded to approve the June 2005 minutes (Heidrick/Coast). Motion carried 4-0.

APPROVAL OF AUGUST 2005 MINUTES: A motion was made and seconded to approve the August 2005 minutes (Heidrick /Coast). Motion carried 4-0.

ADMINISTRATIVE PROCEEDINGS:

LORIE BRINKMAN CASE NO. 04-60

The Respondent, Lorie Brinkman appeared in person. The Board was represented by its attorney, Randall Forbes. Camille Nohe, Assistant Attorney General, appeared as General Counsel to the Board. A court reporter was present. The Board filed a Petition on July 26, 2005 to revoke, suspend or otherwise limit the license of Ms. Brinkman. The Board also filed a denial of Ms. Brinkman's renewal. Both issues were taken up by the Board. After hearing testimony, the Board adjourned for deliberations. The Board returned from deliberations and Camille Nohe read a statement that the Board was concerned about the Respondent's mental health. The Board advised the Respondent

that they were going to reinstate the license for the purpose of revoking said license. The Board ordered the licensed revoked and reinstatement of Respondent's license will not be considered by the Board until such time as the Respondent provides verification of psychiatric or psychological treatment and a recommendation by the treating psychiatrist or psychologist that Respondent is able to practice safely and competently. Camille Nohe will draft a Final Order for the Board's signature.

ADJOURNMENT:

The Board adjourned for a five-minute recess. (Coast /Arck). Motion carried 4-0.

RECONVENE:

The Board reconvened at 10:25 a.m.

LINCARE, INC., CASE NO. 05-01

The Respondent was not required to appear. The Board appeared by and through its attorney Randall Forbes. This case was tabled at the August meeting so that staff could provide additional information to the Board. The proposed discipline in the Stipulation was a \$500 fine for dispensing out of date medications to a person without being registered with the Board as a pharmacy. The Board's Executive Director contacted the Respondent and requested additional information in the form of a letter. The Respondent responded to the Board with a letter dated September 6, 2005. The Board indicated that the Respondent's arrangements with local pharmacies were not addressed to their satisfaction. The Board would like more detailed information stating how the licensee is going to handle their patients in the future. The Board would like to have an operational person appear at the next meeting so that all questions can be answered. The Board directed that Board staff to check each location in Kansas to find out whether they are properly licensed. A motion was made and seconded to table Case No. 05-01 until the November Board meeting. (Coast/Arck). Motion carried 4-0.

KAREN MOEDER CASE NO. 05-25

The Respondent, Karen Moeder, appeared in person. The Board was represented by its attorney, Randall Forbes. A stipulation and final agency order was provided to the Board for final approval. A Consent Agreement not to practice was filed in May and the Board was provided with background information. The proposed discipline in the Stipulation is a required 5-year contract with CIPP and includes the typical language that respondent stay in compliance and that CIPP provide information to the Board. Max Heidrick requested information as to whether the Respondent would be restricted from being a PIC and whether she would be prevented from working alone. Bill Bays, CIPP Committee President, advised the Board that it is a standard provision of all CIPP agreements that these restrictions are included. A motion was made and seconded to accept the Stipulation. (Arck/Coast). Motion carried 3-0.

DUANE ILES, CASE NO. 05-37

The Respondent, Duane Iles, did not appear. The Board was represented by its attorney, Randall Forbes. Camille Nohe, Assistant Attorney General, represented the Board as its General Counsel. The Board considered a Petition to Revoke, Suspend or Otherwise Limit the Licensure based on a failure to maintain records, failure to fill in strict compliance, and engaging in behavior that demonstrates a manifest incapacity or incompetence to practice pharmacy. Mr. Iles provided the Board with a letter advising that he would cease practice effective September 15, 2005. Mr. Forbes advised the Board that he had sent notice for a formal hearing scheduled today and that he was ready to proceed. Mr. Iles turned in his license to practice on Friday, September 17, 2005.

The Board found the Respondent to be in default and proceeded with the hearing. Jim Kinderknecht testified to the events regarding this investigation. The Board deliberated and determined that a default order should be issued. The Board acknowledged that Mr. Iles had submitted a letter with the intent to surrender his license to the Board. The Board did not accept the surrender and hereby revoked the license. The Board also accessed a fine in the amount of \$5000 per count for a total fine of \$15,000. The Respondent will have seven days to ask that the default be set aside. Camille Nohe will draft an Order setting out the wishes of the Board.

The Board has drugs in its possession that was confiscated from Iles Pharmacy. The Board directed staff to explore the possibility of sending drugs to a reverse distributor or EZ Return. Any money collected after Board costs should be sent to the Respondent. If the drugs are unable to be returned for credit/destruction the drugs shall be destroyed by the Board of Pharmacy.

RECESS: The Board recessed for lunch until 1:30 p.m. (Coast/Arck). Motion Carried 4-0.

RECONVENE: The Board reconvened at 1:30 p.m.

THOMAS HOLROYD, CASE NO. 03-58

The Respondent, Thomas Holroyd, appeared in person. The Board was represented by its attorney, Randall Forbes. The Stipulation and Final Agency Order was presented to the Board for final aproval. Jim Kinderknecht provided the Board with background information regarding the case. The proposed discipline in the Stipulation required the assessment of a \$10,000 fine for filling prescriptions on multiple occasions without a prescription or verification from a physician. The Respondent also failed to maintain records. Mr. Holroyd admitted to the Board that the employee/nurse/and doctor did not call in the prescriptions even though he recorded that prescriptions were phoned in. Mr. Holroyd said that the prescriptions were originally written by the physician and he just okayed the refills without authorization. The patient in question was a long time patient of 10-15 years and he has no explanation for what he did. Some of the medications required patient monitoring and this was not done so the patient was at risk. A motion was made and seconded to adjourn into executive session to deliberate. (Heidrick/Arck). Motion carried 4-0.

A motion was made and seconded to amend the Stipulation adding the requirement that the Respondent pass and complete a PIC test within 30 days. The Respondent shall have at least a passing score of 85 percent. (Gilstrap/Coast) Motion carried 4-0.

JILL CARRELL, CASE NO. 05-38

The Respondent, Jill Carrell, appeared in person. The Board was represented by its attorney, Randall Forbes. The Respondent has applied for a license in Kansas. She is currently licensed in Missouri with restrictions. The proposed agreement was a Stipulation requiring a 5-year contract with CIPP and included the typical language that the Respondent stay in compliance and that CIPP provide information to the Board.

The Board made a motion to accept the Stipulation and Final Order (Arck/Heidrick). Motion carried 3-0. The Kansas Board will make efforts to work with Missouri since duplication of services may not be necessary.

RICK STONE, CASE NO. 05-34

The Respondent, Rick Stone, did not appear. The Board was represented by its attorney Randall Forbes. The proposed discipline in the Stipulation provided for a fine of \$1200 for dispensing Prometh with codeine over the counter. There was also a recommended fine of \$500 for failure to register technicians.

A motion was made and seconded to accept the Stipulation. (Heidrick/Coast). Motion carried 4-0.

BAXTER DRUG, CASE NO. 05-29

The Respondent did not appear. The Board appeared by and through its attorney Randall Forbes. The proposed discipline was a stipulation, which provided a fine of \$500 for failure to register technicians. A motion was made and seconded to accept the Stipulation (Heidrick/Coast) Motion carried 4-0. (Note: Terry Martin appeared on behalf of Baxter Drug after the conclusion of the case.)

MICHAEL MORRISON, CASE NO. 05-32

The Respondent did not appear. The Board appeared by and through its attorney, Randall Forbes. The case involved a misfill and the question was whether there was counseling. The proposed Stipulation required a fine of \$500 for failure to counsel. Through negotiations the Respondent requested that the admission of guilt be removed and that the "wording" the Respondent does not contest the findings be added.

A motion was made by the Board to accept an amended Stipulation permitting the Respondent to enter a plea of no contest to the charges. (Heidrick/Coast) Motion carried 4-0.

CVS PHARMACY, CASE NO. 05-30

A motion was made to table this case until the November Board meeting. (Coast/Heidrick). Motion carried 4-0.

ADJOURNMENT:

The Board adjourned for a five-minute break. (Heidrick/Coast). Motion carried 4-0.

RECONVENE:

The Board reconvened at 3:10 p.m.

DISCUSSION REGARDING COMPOUNDING REGULATIONS:

The Board discussed specific questions that the Department of Administration had regarding definitions. Shirley Arck is going to provide some of this information to Randy Forbes.

Shirley Arck had some additional issues that were provided to the Board in writing prior to the meeting. It was determined that Dr. Arck and Jeff Thompson would work together to resolve the issues that she had set out. Max Heidrick had additional questions as to whether the regulations would apply to a physician compounding in their office. The Board discussed some of the jurisdictional issues. There was also discussion regarding the physician/patient relationship, the definition of purified water, and whether a pharmacy technician could verify and whether the language in the regulations covered interns. The Board also discussed the definition of "batch".

The regulations have been to the Department of Administration and they were returned with questions. The Board will continue to work with Randy Forbes on proceeding with having the regulations approved.

The Board acknowledged the hard work that Jeff Thompson had put into drafting this regulation.

SPECIAL PRESENTATION TO JEFF THOMPSON, R.PH. AND FRANK WHITCHURCH, R.PH.

A special presentation was made to Jeff Thompson and Frank Whitchurch for their service and leadership to the profession of pharmacy. Jeff served as a Board member from May of 2002 through June of 2005. He served as President from June 2004 to June 2005. Frank Whitchurch served as a Board member from May of 2002 through June of 2005. Frank served as Vice-President in both 2004 and 2005. The Board acknowledged the voluntary service of both individuals.

TELEPHARMACY:

The Board reviewed whether to continue with the telepharmacy issue. The Board would like to use telepharmacy but in a controlled manner. They do not want to permit it until we have a law on the books. The Board felt that Kansans would be best served if there was draft legislation that gives the Board broad authority. Randy Forbes advised the Board that they cannot approve for one and limit another under our current laws. Randy

suggested that we enact a statute that authorizes the Board to promulgate regulations. The Board has some models from other states. Mike Coast and Merlin McFarland will work on the language for a future meeting.

INSTITUTIONAL DRUG ROOMS

Max Heidrick provided copies of draft regulations for Institutional Drug Rooms. His concern was that there was dispensing from stock bottles. There might be a necessity to exempt oral liquid medications since they can't all be prepackaged. The regulation also needs to require the name of the person phoning in the order. It was also suggested that lot numbers be required as well as the requirement that the pharmacist check the patient profile to ensure a mechanism that provides drug /disease, drug / drug, and drug /allergy review. A written policy and procedure should be required. The Board approved moving forward with the regulation after the discussed changes are made.

DEA 222

The federal law has changed regarding submission of electronic DEA 222 forms. The Board authorized the staff to change the state regulation.

INCIDENT REPORT UPDATE

Melissa Martin provided information regarding problems with chain pharmacies not having hard copy incident reports on file. The Board had authorized Walgreens to test the STARS software. The inspectors advised the Board that Corporate wasn't responding quickly with requested copies of incident reports. Some of the Walgreens pharmacists can't get on the STARS software correctly. The Board has also experienced other chain pharmacies failing to keep hard copies in the store even though they have not received a waiver. The Board terminated the test project for Walgreens since it is not successful and stated that all pharmacies need to have 5 years of hard copy incident reports in their store. If the pharmacy is not in compliance they will be issued a fine. (Heidrick/Coast). Motion carried 4-0.

BUDGET

The Board reviewed the current budget. The Executive Director advised the Board that there were not going to increase fees at this time. The Board will continue watching trends but at this time an increase is not warranted.

APPROVAL OF LICENSES

A motion was made and seconded to approve the pharmacist licenses issued by the Board since the June meeting. (Coast/Gilstrap) Motion carried 4-0.

A second motion was made and seconded to approve pharmacy registrations issued by the Board since the June meeting. (Gilstrap/Arck) Motion carried 4-0.

ADJOURNMENT:

The Board adjourned at 4:30 p.m. The Board will reconvene at 8:00 a.m. on September 21, 2005.

Wednesday, September 21, 2005

MEMBERS PRESENT: Merlin McFarland, R.Ph., President; JoAnne Gilstrap, R.Ph., Vice-President; Max Heidrick, R.Ph., Dr. Shirley Arck, R.Ph., and Michael Coast.

STAFF PRESENT: Debra Billingsley, Executive Director; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; LaTonyua Rice, Pharmacy Inspector; and Randall Forbes, General Counsel.

OTHERS PRESENT: See Attached listing

MEETING CALLED TO ORDER:

Merlin McFarland called the meeting to order at 8:00 a.m.

PHARMACY TECHNICIAN RATIO

The Board received two letters regarding the Pharmacy Technician ratio. One letter was from the Health System Pharmacists and the other was written jointly KPhA and the KS Federation of Chain Pharmacists. The Board has moved forward with a temporary regulation and a permanent regulation setting the ratio at two to one. This discussion is whether the ratio should be increased in the future.

The information collected indicated that the majority of licensees support a three to one ratio. There was discussion as to whether national certification should be required if the ratio is increased. JoAnne Gilstrap stated that changes to the technician ratio affect quality and safety to the patient and that any change made by the Board should require a super majority of 5 to 1. Randy Forbes advised the Board that a requirement of a super majority would take a legislative change to the statute. The Board discussed seeking a statutory change instituting a requirement of a super majority by the Board regarding the ratio. The Board discussed changing the technician law so that a test would not be required prior to hiring and registration. If this change is made then the Board could also pursue a super majority (five votes) regarding this issue.

The Board noted that at the Kansas Pharmacists 125th Annual Meeting there wasn't a lot of discussion or objections regarding changing to three to one. Standardization of testing such, as the PCTB would guarantee that all technicians has the same training. The Board discussed requiring all three technicians be certified in order to take advantage of the 3 to 1. It was pointed out that hiring might be difficult as well as training of new technicians since a new person would generally not have certification.

John Kiefhaber spoke representing the coalition. He stated that there has been extensive debate on this issue. The real conclusion in addition to what is stated in letters is that it would be safe to go three to one. New technology is in place and with more time being required for pharmacist to meet with patients the volume is rising. Part D will also

require the pharmacist to develop therapy management. With proper management and better equipment and organization most feel that they can handle 3 to one. You would be free to stay at 2 to 1 if that was your choice.

The Board indicated that they wanted to improve technician competency in Kansas. The Board agreed that the regulation should be amended to raise the ratio to 3 to 1 and that certification should be required in the future. The Board staff was directed to work on draft language for further discussion.

CANCER DRUG REPOSITORY REGULATIONS

Max Heidrick has been working with staff to draft regulations for the Cancer Drug Repository. They have reviewed information from other states and there are many questions regarding who can participate and who should be eligible. Max indicated that he would want something in the regulations that require interaction checks and review of the patient profile. The Board discussed the fact that this was a popular regulation that could provide assistance to many people. The Board agreed that they should continue to work on the regulation so that they could make sure all safety precautions were in place before it was put into action.

ADJOURN: The Board took a break for approximately 15 minutes.

RECONVENE: The Board reconvened at 10:20 a.m.

INVESTIGATIVE REPORTS:

Presented by JoAnne Gilstrap. There were no comments regarding closed cases.

DISCUSSION REGARDING DRUG DIVERSION PENALTIES

The investigative member, JoAnne Gilstrap, has been reviewing numerous drug diversion penalties. We give a penalty to all persons who violate our laws except for drug diversions. These people are simply being enrolled to CIPP. JoAnne wanted input from the Board as to whether the individual should be charged a penalty. Max Heidrick gave some history regarding fines. They used to give \$250,000 fines and some of it would be waived but the Board didn't feel that they were achieving an end result that was appropriate. Therefore, the Board quit using this approach.

The Board acknowledged that to say the licensee is addicted and send them to CIPP might not provide justice. JoAnne asked whether the investigative member needed to stick with that standard or whether we should be reviewing more on a case by case basis. If large quantities of drugs are missing the Board should try to find where the drugs went and whether criminal charges should be filed. If someone admits they are addicted and work with CIPP they should not go back to work unless they are ready. That does put a financial penalty on the licensee. If you can prove that the licensee sold the drugs then they should receive a stricter penalty than CIPP enrollment.

JoAnne Gilstrap stated that the Board is very fortunate to have CIPP. After reading the letter from Bill Bays, JoAnne stated that she could see that not everyone should be

financially penalized. However, the Board agreed that the investigative member could use their judgment when reviewing these cases and that there was no standard set. The penalty should be based on the individual facts of each case.

Nancy Corkins wanted to make sure that the Board realized that many people have legal issues when they come before the Board. If they are in high dose cases they may never work in this profession again. There is something to be said for deterring violators but there used to be a high case of suicides. These people have already lost their job and their family and sometimes giving them a penalty that is harsh pushes them over the edge. The Board agreed that they would use high standards of accountability but assured everyone that they would use a balanced sensible approach in cases involving impairment.

BOARD REPORTS:

Michael Coast advised the Board that he had concerns that stock bottles were coming out of hospitals with just the patient name on them. The patient often ended up back in long term care with a medication bottle that was not properly labeled. Mike stated that when he finds them he is destroying them. The Board asked staff to put something in the newsletter regarding this issue.

Shirley Arck thanked staff for getting information out quickly regarding the Board's relaxation of regulations during the hurricane emergency. The Board discussed relaxing rules for 60 days from the date the Order was issued. If there are other emergencies in the future the Board will continue to review and address those situations.

PRESENTATION BY US DEPT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Tracy Meder, Investigative Analyst, presented information regarding OIG exclusions. OIG can provide administrative sanctions against health care providers who are involved in providing federally funded health care programs. Ms. Meder provided information to the Board explaining how the exclusions work and how the Board can provide assistance to the OIG.

BOARD REPORTS

Max Heidrick thanked Joanne Gilstrap, Randy Forbes and staff for getting the large number of disciplinary cases concluded in a short amount of time. Max offered the suggestion that the Board should put a requirement in Stipulations for drug diversion that an initial inventory be conducted before the respondent begins employment. It would be part of stipulation that before they are hired that the store would have to conduct an initial inventory. This would provide additional safeguards. The Board discussed this and agreed that it would be a good addition to the Stipulations.

JoAnne Gilstrap suggested that with the new compounding regulations that it would be good for the staff to have compounding training. The Board has been offered training and she urged the staff to look for additional training opportunities.

JoAnne asked whether it would be appropriate to look at the inspector's duties to determine whether we have enough staff to complete the agency mission. Deb Billingsley did advise the Board that the legislature would not approve any additional staffing unless the Board had numbers to back up the amount of work that the inspectors are doing. At this time, the investigative cases have not really seen a dramatic increase and there has not been a dramatic increase in the number of licensees.

The issue of central input as it relates to shared service and the pharmacist technician ratio should be reviewed. This issue needs to be placed on the November agenda to see if the Board wishes to make any changes. The hurricane emergency raised some issues of how the regulation is being used and the Board may not have intended such broad interpretation.

Merlin McFarland

Incident reports are a key ingredient in correcting pharmacy errors. The pharmacy needs to figure out how to fix the error. Slowing down is a symptom and not a solution. The pharmacist needs to document how he is going to slow down. Board staff should offer suggestions on how a person can correct errors and keep improving on this.

Merlin reported that he went to NACDS Pharmacy and Technology Conference. It was very enlightening and he encouraged others to go in the future. Advances in technology are going to allow a lot to happen and we need to be aware of it. We are seeing more technology also with Central fill and NDC.

STAFF REPORTS

LaTonyua Rice

LaTonyua advised the Board that the Wichita Health Department thanked the Board for their quick response regarding evacuees in Wichita. The Board acknowledged that LaTonyua took immediate action in visiting with the Health Department to see what their needs were.

ADJOURNMENT: The Board adjourned at 11:30 a.m.